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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,690	03/15/2002	Stephen Grimes	1102865-0302	6943

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WHITE & CASE LLP  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER
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KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/098,690

Applicant(s)

GRIMES ET AL.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meier (US Pat. No. 5,262,053) in view of Moller (US Pat. No. 5,620,605). Meier teaches a system comprising an filter device (2) with ultrafiltration membrane, a reaction vessel (7) connected to the filter device (2), a backwash source (18) connected to the filter device (10) and a pump (9) interconnected between the filter device (2) and the reaction vessel (7) (see figure 1; col. 5, line 61 – col. 7, line 18). Meier further teaches that the reaction vessel (7) contains a tanning agent and/or protein and stabilizer i.e. reactant (see col. 2, line 3 –30; col. 6, lines 40-42). Claim 1 essentially differs from the apparatus of Meier in reciting a backwash reservoir. Meier teaches that backwash source is water or cleaning liquids which is directed to the permeate side of the membrane (see col. 6, lines 11-15; col. 7, lines 10-17). Moller teaches a system comprising ultrafiltration membrane device(13) with a backwash tank (18) for backwashing fluid to the permeate side of membrane to remove contaminants from the membrane (see figure 1; col. 5, lines 64-65; col. 11, lines 21-58; col. 13, lines 13-48). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Meier to include a backwash reservoir containing water or cleaning liquids connected to the ultrafiltration membrane device (2) for effectively storing the backwash fluid to backflush the membrane as suggested by Moller. Regarding claim 3, Meier teaches a three way valve (17) selectively interconnected and situated between the reaction vessel (7) and the filter device (2) and the

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backwash source (18) (see figure 1; col. 6, lines 11-15; col. 6, line 56 - 17). Regarding claim 5, Meier teaches that the filter device (2) is connected to the permeate reservoir (19) (see figure 1; col. 5, line 68 – col. 6, line 2). Regarding claim 6, Meier teaches that the unfiltered medium e.g. protein is pumped from the reaction vessel (7) through the filter (2) and then return into the reaction vessel (7) (see col. 7, lines 37-39) in that the reaction vessel (7) is a receptacle of the purified concentrate product from the filter (2).

3. Claims 1 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervan et al (US Pat. No. 4,443,540) in view of Moller (US Pat. No. 5,620,605). Chervan et al teach a system comprising an ultrafiltration membrane device (90), a reaction vessel (80) connected to the membrane device (90), and a pump (82) interconnected between the membrane device (90) and the reaction vessel (80) (see figure; col. 3, line 56 – col. 4, line 24; col. 6, lines 1-19). Chervan et al further teach that the reaction vessel (80) contains a protein material and enzyme i.e. (see col. 3, line 66 – col. 4, line 2). Claim 1 essentially differs from the apparatus of Chervan et al in reciting a backwash reservoir being fluidly connected with the ultrafiltration/concentration means. Moller teaches a system comprising ultrafiltration membrane device(13) with a backwash tank (18) for backwashing fluid to the permeate side of membrane to remove contaminants from the membrane (see figure 1; col. 5, lines 64-65; col. 11, lines 21-58; col. 13, lines 13-48). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Chervan et al to include a backwash reservoir containing water or cleaning liquids connected to the ultrafiltration membrane device (90) for effectively storing the backwash fluid to backflush the membrane to remove contaminants from the membrane as suggested by Moller. Regarding claim 5, Chervan

et al teach that the membrane device (90) is connected to a collection means for permeate (see col. 4, lines 21-24). Regarding claim 6, Chervan et al teach that the insufficiently hydrolyzed protein material rejected by the membrane filter (90) is recycled back to the reactor vessel (80) (see col. 4, lines 11-21).

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meier or Chervan et al as applied to claim 1 above, and further in view of Breslau et al (US Pat. No. 4,986,918) and AMICON Brochure re Spiral-Wound/Hollow Fiber System (hereinafter referred to as AMICON). Meier or Chervan et al teach the ultrafiltration system as described in above paragraphs 2-3. Meier teaches a microporous membrane in tube form (see col. 8, lines 64-67). Chervan et al teach hollow fiber membranes (see col. 6, lines 20-25). Claim 4 essentially differs from the systems of Meier or Chervan et al in reciting a spiral diafiltration cartridge as the ultrafiltration means. Breslau et al teach that membranes used in ultrafiltration may be of various configurations such as hollow fiber, flat sheet, spiral wound or tubular (see col. 1, lines 43-46). AMICON teaches a ultrafiltration system comprising an ultrafiltration membrane device of a spiral wound/hollow fiber diafiltration cartridge for efficient processing of macromolecular solutions or cell suspensions (see page 54, 16, 24). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute a spiral wound/hollow fiber diafiltration cartridge for tubular or hollow fiber membrane of Meier or Chervan et al for efficient processing of macromolecular solutions as in the solutions treated in Meier or Chervan et al as suggested by AMICON and Breslau et al.

5. Applicant's arguments with respect to claims 1 and 3-6 have been considered but are moot in view of the new ground(s) of rejection. Applicants added new limitation in claim 1 that

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the reaction vessel comprises a protein and a reactant for modification and/or conjugation thereof. This new recitation has been met by Meier and Chervan et al as rejected in above paragraphs 2-3.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

JK  
June 12, 2006